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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,860	07/23/2003	Dale N. Larson	D-26	7992
21253	7590	07/11/2006		
CHARLES G. CALL			EXAMINER	
68 HORSE POND ROAD			BOWERS, NATHAN ANDREW	
WEST YARMOUTH, MA 02673-2516				
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/625,860	LARSON ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Nathan A. Bowers	1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on 23 July 2003.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 1-18 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-18 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 23 July 2003 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	6) <input type="checkbox"/> Other: _____.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 1) Claims 1 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "small" in claims 1 and 12 is a relative term which renders the claim indefinite. The term "small" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Essentially any object of any size could be considered "small" in the absence of appropriate guidelines.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2) Claims 1, 3-7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Shimazaki (US 5957038).

Shimazaki discloses an apparatus for intermixing small objects and a liquid comprising at least one receptacle (Figure 1:2) for receiving and retaining the small objects. The lower surface of the receptacle includes pores (Figure 1:6) that permit the liquid to flow through the receptacle and intermix with the small objects. This occurs when the receptacle is inserted into a vessel (Figure 1:1) that holds the liquid. This is disclosed in column 1, lines 26-36 and column 3, lines 10-50. The receptacle is provided with a handle (Figure 1:3), which allows one to immerse the receptacle in the liquid contained in the vessel any number of times. Furthermore, it is believed that the receptacle is constructed of a material that is chemically inert with respect to the liquid and the small objects.

3) Claims 1, 3-10, 12, 15, 16 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Frondoza (US 20050147959).

With respect to claims 1, 3-7, 10, 12, 15 and 16, Frondoza discloses an apparatus for intermixing small objects with a liquid comprising a plurality of receptacle wells (Figure 1:3) containing the small objects. Each of the wells has a lower portion (Figure 1:4) that is permeable to permit the flow of liquid therethrough. A vessel (Figure 1:5) containing a solution is also provided, as well as means for repeatedly inserting the receptacles into the solution held in the vessel. The receptacle can then be withdrawn

to cause the liquid to flow outwardly through the lower portion while retaining the small objects. This is disclosed in paragraphs [0037]-[0052] and [0064]-[0073].

With respect to claims 8, 9 and 18, Frondoza discloses the apparatuses in claims 1 and 12 wherein the small objects comprise cells cultured upon microcarriers. This is disclosed in paragraphs [0051] and [0052]. Paragraphs [0064]-[0073] further indicate that the cells are subjected to pharmaceuticals in order to study their affects on the activity and health of the cells.

4) Claims 1, 3-7, 10, 12, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Feygin (US 6315957).

Feygin discloses an apparatus for intermixing small objects with a liquid comprising a plurality of receptacles (Figure 2:222) having a lower portion (Figure 2:226) that is permeable to permit the flow of liquid therethrough. A vessel (Figure 3:330) is additionally provided for containing a solution. The receptacles are repeatedly inserted into the solution held by the vessel in order to allow the solution to permeate through the pores located at the lower portions of the receptacles. The pores are sized so that they allow the passage of fluids, but not the passage of the small objects. This is disclosed in column 1, line 58 to column 2, line 38 and column 3, line 15 to column 4, line 19. Means for repeatedly moving the receptacle in and out of the vessel are described in column 4, line 53 to column 5, line 21 and in Figure 5.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5) Claims 2, 11, 13, 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feygin (US 6315957) as applied to claims 1 and 12 above, and further in view of Reeve (WO 9112079) and/or Valkirs (US 6348318).

Feygin discloses the apparatuses set forth in claims 1 and 12 as set forth in the 35 U.S.C. 102 rejections above. In addition, Feygin discloses in column 6, lines 10-20 that affinity beads are used as small objects that facilitate a reaction with the solution as it moves through the permeable bottom of the receptacle from the vessel. Feygin, however, does not expressly state that the liquid solution is a lysate that contains proteins that become bound to the affinity beads when the solution and the affinity beads are intermixed.

Reeve discloses a method of purifying proteins. Reeve indicates on pages 4-6 that it is known in the art to remove proteins from a cell lysate by allowing them to bind to the surfaces of a plurality of affinity beads.

Valkirs discloses a method that involves the use of affinity beads that selectively bind to protein analytes in solution. The surfaces of the beads are covered with a moiety that attaches to analytes in order to form a target complex. The beads can then be removed from the solution as a means by which to obtain a purified product. This is disclosed in column 1, line 52 to column 2, line 52.

Feygin, Reeve and Valkirs are analogous art because they are from the same field of endeavor regarding filtering and protein purification systems.

At the time of the invention, it would have been obvious to the use the device proposed by Feygin in order to purify protein analytes in a lysate solution. Feygin

already teaches that the device is capable of allowing particles, such as proteins, in a solution to move through the porous bottom of the receptacle in order to interact with affinity beads. Therefore, one skilled in the art would have been fully capable of implementing the ideas regarding protein purification disclosed by Reeve and/or Valkirs in order to create a system in which the receptacle is allowed to interact with a lysate solution and remove protein targets. Absent a showing of criticality, it would have been obvious to utilize the affinity beads disclosed by Feygin as a means by which to bind to proteins in a lysate that are allowed to filter through a permeable barrier, especially since Reeve and Valkirs indicate that this is an effective process that is known in the art.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The Robinson (US 6890740) and Tsinberg (US 20040191891) references teach the state of the art regarding receptacles comprising permeable portions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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